K020659

MAR 2 9 2002

PART VIII. 510(K) SUMMARY

Submitter by: SSL Americas, Inc.
3585 Engineering Drive
Norcross, Georgia 30092

Contact Person: Joyce Ning
Vice President, Regulatory Affairs
Phone: (770) 582-2152

Date Prepared: February 15, 2002

Proprietary Name: Durex® latex condom with male desensitizer lubricant

Common Name: Latex Condom

Classification Name: Condom (21 CFR § 884.5300)

Predicate Device: DUREX® Hispano Ico Latex Condom (K952415) and Male Condom with Desensitizer (K822088)

Description of the Device: DUREX® Latex Condom with Male Genital Desensitizer Lubricant is made of a natural rubber latex sheath with lubricant containing Benzocaine, an over-the-counter drug recognized as safe and effective by US FDA under 21 CFR 5300 for condom and 21 CFR Part 348 for external analgesic drug products for over-the-counter human use. The condom is a straight-walled, nipple-end condom with the nominal length of 180 mm and width of 52 mm as required by ASTM D-3492-97.

Intended Use of the Device: DUREX® Latex Condom with Male Genital Desensitizer Lubricant has the same intended use as the predicate condom. It is used for contraception and for prophylactic purposes to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases (STDs). In addition, the male genital desensitizer lubricant on the condom helps in temporarily prolonging the time till ejaculation.

Technological Characteristics: Both the proposed device and the predicate device are of the similar design meeting ASTM Standard (D3492) specification for Rubber Contraceptives (Male Condoms). Both are straight-walled, nipple-end, lubricated made with the similar formulation of natural rubber latex. The proposed condom is a modification of the predicate device with variation merely in the lubricant application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Joyce Ning
Vice President Regulatory Affairs
SSL Americas, Inc.
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P.O. Box 926090
NORCROSS GA 30092-9214

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Re: K020659
Trade Name/Device: DUREX® Latex Condom with Male Genital Desensitizer Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: February 28, 2002
Received: March 1, 2002

Dear Ms. Ning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Please be advised that, as of March 25, 1998, labeling for latex condoms (21 CFR §884.5300 and §884.5310) must comply with Use Labeling for Latex Condoms: Expiration Dating, 21 CFR 801.435. Therefore, an expiration date, supported by test data developed under the conditions specified in §801.435(d), must be displayed prominently and legibly on condom labeling. For condoms with spermicidal lubricant, the effective shelf life of the spermicide must be compared with the shelf life of the condom and labeled with the earlier of the two expiration dates. Although supporting data is not to be provided in your 510(k) submission, §801.435(j) requires that you maintain this data and that it be available for inspection by FDA. Furthermore, §801.435(e) requires that if your real-time test data fails to confirm the shelf life estimated by the methods in §801.435(d), then you must relabel all product to reflect the actual shelf life. Condoms are not to be labeled with an expiration date that gives a shelf life more than five years.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597,or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K020659

PART V. INDICATIONS FOR USE STATEMENT

3.0

Indications for Use Statement

Applicant: SSL-Americas, Inc.

510(k) Number (if known):* K020659

Device Name: DUREX® Latex Condom with Male Genital Desensitizer Lubricant

Indications for Use:

The DUREX® Latex Condom with Male Genital Desensitizer Lubricant is used for contraception and for prophylactic purposes to help reduce the risk of pregnancy and the transmission of sexually transmitted diseases. The male genital desensitizer lubricant on the condom helps in temporarily prolonging the time until ejaculation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-The-Counter Use** ✓

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020659